

Data Evaluation Report on the Toxicity of Neudorff's Insecticidal Soap Concentrate (AI: potassium salts of fatty acids) to Terrestrial Vascular Plants: Vegetative Vigor

PMRA Submission Number {.....}

EPA MRID Number 48402302

Data Requirement: PMRA Data Code: 9.8.4 (TGAI) or 9.8.6 (EP)
EPA DP Barcode: 388713
OECD Data Point: IIA 8.12 (TGAI) and IIIA 10.8.1.1 (EP)
EPA Guideline: 850.4150 Tier II

Purity: 46.8%

Test material: Neudorff's Insecticidal Soap Concentrate (AI: potassium salts of fatty acids)

Common name

Chemical name: IUPAC

CAS name

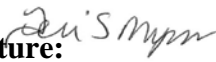
CAS No.

Synonyms:


Primary Reviewer: Joan Gaidos
Senior Scientist, Cambridge Environmental, Inc.

Signature: 
Date: 12/19/11

Secondary Reviewer: Teri S. Myers
Senior Scientist, Cambridge Environmental Inc.

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Date: 12/21/11

Primary Reviewer: Stephen Carey, Biologist
EPA/OCSP/OPP/EFED/ERB6

Signature: 
Date: 6/19/12

Reference/Submission No.: {.....}

Company Code {.....} [For PMRA]

Active Code {.....} [For PMRA]

Use Site Category: {.....} [For PMRA]

EPA PC Code 079021

CITATION: Martin, J.A. 2011. Neudorff's Insecticidal Soap Concentrate – Vegetative Vigor Test Following U.S. EPA OPPTS Draft Guideline 850.4250 (Tier II). Unpublished study performed by Smithers Viscient, Wareham, Massachusetts. Study no. 13989.6111. Study sponsored by W. Neudorff GmbH KG, Great Falls, Virginia. Study completed February 15, 2011.

DISCLAIMER: This document provides guidance for EPA and PMRA reviewers on how to complete a data evaluation record after reviewing a scientific study concerning the toxicity of a pesticide to terrestrial vascular plants. It is not intended to prescribe conditions to any external party for conducting this study nor to establish absolute criteria regarding the assessment of whether the study is scientifically sound and whether the study satisfies any applicable data requirements. Reviewers are expected to review and to determine for each study, on a case-by-case basis, whether it is scientifically sound and provides sufficient information to satisfy applicable data requirements. Studies that fail to meet any of the conditions may be accepted, if appropriate; similarly, studies that meet all of the conditions may be rejected, if appropriate. In sum, the reviewer is to take into account the totality of factors related to the test methodology and results in determining the acceptability of the study.

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EXECUTIVE SUMMARY:

The effect of **Neudorff's Insecticidal Soap Concentrate (AI: potassium salts of fatty acids)** on the vegetative vigor of monocot (corn, *Zea mays*; oats, *Avena sativa*; onion, *Allium cepa*; and ryegrass, *Lolium perenne*) and dicot (common bean, *Phaseolus vulgaris*; cucumber, *Cucumis sativa*; oilseed rape, *Brassica napus*; radish, *Raphanus sativus*; soybean, *Glycine max*; and Tomato, *Lycopersicon esculentum*) crops was studied at nominal concentrations of 0 (negative control), 4.07, 8.14, 16.27, 32.54, and 65.08 lbs a.i./A; equivalent to measured concentrations of 0, 4.24, 8.10, 16.21, 32.42 and 68.08 lb a.i./A (cucumber, oat, bean, corn, onion, radish and ryegrass) and 0, 4.30, 6.86, 16.21, 33.04 and 68.57 lbs a.i./A (oilseed rape, soybean and tomato).

The growth medium used in the seedling emergence test was a soil from Rochester, Massachusetts (sandy loam, pH 6.0, organic matter 2.2%). On day 14 the surviving plants per pot were recorded and cut at soil level for measuring the plant height and dry weight.

In the vegetative vigor test, survival was not affected. Height was affected in corn, cucumber, oilseed rape, soybean and tomato. Dry weight was affected in corn, common bean, cucumber, oilseed rape, radish, soybean and tomato. The most sensitive monocot species was corn, based on dry weight, with NOAEC and EC₂₅ values of 4.24 and 5.91 lbs a.i./A, respectively. The most sensitive dicot species was oilseed rape, based on dry weight, with NOAEC and EC₂₅ values of <4.30 and 18.5 lbs a.i./A, respectively.

Morphological abnormalities (e.g. chlorosis of leaves) were determined based on a range from 0 to 100, where 0 indicates no injury or abnormality and 100 indicates complete effect (dead plant; not further described). The mean abnormality rating in the control was 3. Onion, corn, soybean, oilseed rape, bean, tomato and radish exhibited effects up to 20 and cucumber up to 60; oat and ryegrass were not affected.

This toxicity study is scientifically sound and fulfills EPA guideline requirements for a vegetative vigor toxicity study with terrestrial plants. The study is classified as ACCEPTABLE.

Maximum Labeled Rate: Not reported

Results Synopsis

Monocot

EC ₅₀ /IC ₅₀ : >68.08 lbs a.i./A	95% C.I.: N/A
EC ₂₅ /IC ₂₅ : 5.91 lbs a.i./A	95% C.I.: 1.11-31.45 lbs a.i./A*
EC ₀₅ /IC ₀₅ : 0.082 lbs a.i./A*	95% C.I.: 0.0012-5.42 lbs a.i./A*

* Test concentration and/or 95% confidence interval not bracketed by the tested dose range.

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NOAEC: 4.239 lbs a.i./A

Slope: 0.5225 Std err: 0.3158-1.5125

Most sensitive monocot: Corn

Most sensitive parameter: Dry weight

Dicot

EC₅₀/IC₅₀: 50.31 lbs a.i./A 95% C.I.: 31.93-79.27 lbs a.i./A*

EC₂₅/IC₂₅: 18.50 lbs a.i./A 95% C.I.: 7.93-.43.11 lbs a.i./A

EC₀₅/IC₀₅: 4.38 lbs a.i./A 95% C.I.: 0.83-23.03 lbs a.i./A*

NOAEC: <4.3013 lbs a.i./A

Slope: 1.55 Std err: 0.96-3.97

Most sensitive dicot: Oilseed Rape

Most sensitive parameter: Dry weight

Table 1 (Tier II studies). Summary of most sensitive parameters by species (lbs a.i./A).					
Species	Endpoint	NOAEC	EC₀₅	EC₂₅	EC₅₀
Corn	Dry weight	4.239	0.082*	5.91	>68.57
Onion	Shoot length	68.08	3.57*	>68.08	>68.08
Ryegrass	None	68.08	>68.08	>68.08	>68.08
Oat	None	68.08	>68.08	>68.08	>68.08
Bean	Dry weight	8.104	1.43*	20.72	>68.08
Cucumber	Dry weight	16.208	8.89	23.05	44.70
Oilseed rape	Dry weight	<4.3013	4.38	18.50	50.31
Radish	Dry weight	16.208	13.53	57.27	>68.08
Soybean	Dry weight	16.208	8.84	30.55	>68.57
Tomato	Dry weight	16.208	8.90	21.73	40.40

* Value not bracketed by the tested dose range and/or EC values are not reliable.

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I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: The methods used in conducting this study were based on procedures specified in the U.S. EPA Series 850 – Ecological Effects Test Guidelines OPPTS Number 850.4250 (draft).

COMPLIANCE: Signed and dated GLP, Quality Assurance and No Data Confidentiality statements were provided. This study was conducted in compliance with FIFRA Good Laboratory Practice Standards as published by the U.S. EPA, 40 CFR Part 160 (1989), with the following exception: routine soil and water analyses were conducted at GeoLabs, Braintree, Massachusetts using standard EPA procedures.

A. MATERIALS:

1. Test Material	Neudorff's Insecticidal Soap Concentrate (AI: potassium salts of fatty acids)
Description:	Not reported
Lot No./Batch No. :	PG 5-192-1 (batch no.)
Purity:	46.8% potassium salts of fatty acids
Stability of compound under test conditions:	Analytical verification was performed by analyzing stock solutions with recoveries of 84-110%. Recoveries of nominal fortified control samples were 88.8-99.7%.
Storage conditions of test chemicals:	The test material was stored at room temperature in the dark in a ventilated cabinet.

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Table 2. Physical/chemical properties of Neudorff's Insecticidal Soap Concentrate (AI: potassium salts of fatty acids).		
Parameter	Values	Comments
Water solubility at 20EC	Not reported	
Vapor pressure	Not reported	
UV absorption	Not reported	
pKa	Not reported	
Kow	Not reported	

2. Test organism:

Monocotyledonous species: Corn (*Zea mays*; Truckers Favorite Field Corn), Oats (*Avena sativa*, Jerry), Onion (*Allium cepa*, Granex Yellow Hybrid), and Ryegrass (*Lolium perenne*, LINN).

Dicotyledonous species: Common bean (*Phaseolus vulgaris*, Festina), Cucumber (*Cucumis sativa*, Sweet Marketmore), Oilseed rape (*Brassica napus*, Wichita), Radish (*Raphanus sativus*, Cherriette Hybrid), Soybean (*Glycine max*, Edible Early Hakucho), and Tomato (*Lycopersicon esculentum*, Celebrity Hybrid).

Seed source: Common bean, onion, radish, soybean and tomato were supplied by Park Seed Company, Greenwood, South Carolina; corn supplied by Carolina Biological Supply Company, Burlington, North Carolina; cucumber and oat supplied by Seeds of Change, Santa Fe, New Mexico; oilseed rape supplied by Johnston Grain Company, Enid, Oklahoma; and perennial ryegrass supplied by Granite Seed, Lehi, Utah.

Prior seed treatment/sterilization: Seeds were not treated with fungicides, insecticides, or repellents prior to test initiation.

Historical % germination of seed: Corn, 90%; oats, 91%; onion, NA; ryegrass, 95%; common bean, NA; cucumber, NA; oilseed rape, 90%; radish, NA; soybean, 98%, and tomato, NA.

(NA=Not Applicable, as reported by the study author)

Seed storage, if any: None reported.

B. STUDY DESIGN:

1. Experimental Conditions

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a. Limit test: N/A – conducted as a Tier II test

b. Range-finding study: A range-finding study was not reported.

c. Definitive Study: The in-life portion of the test with bean, corn, cucumber, oat, onion, radish and ryegrass was conducted from December 2 to 20, 2010. The portion of the test conducted with oilseed rape, soybean and tomato was conducted from December 29, 2010 to January 17, 2011.

Table 3: Experimental Parameters - Vegetative Vigor		
Parameters	Vegetative Vigor	
	Details	Remarks
		<i>Criteria</i>
Duration of the test	14 days	<i>Recommended test duration is 14-21 days.</i>
Number of seeds/plants replicate	<u>Bean, corn, cucumber, oilseed rape, soybean</u> 3 seedlings per replicate <u>Oat, onion, and ryegrass</u> 8 seeds per replicate <u>Soybean, and tomato</u> 5 seeds per replicate	<i>Five plants per replicate are recommended.</i>
Number of plants retained after thinning	Not reported.	
<u>Number of replicates</u>	<u>Oat, onion and ryegrass</u>	

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Table 3: Experimental Parameters - Vegetative Vigor		
Parameters	Vegetative Vigor	
	Details	Remarks
		<i>Criteria</i>
Control: Formulation blank: Treated:	4 N/A 4 <u>Radish and tomato</u>	<i>Four replicates per dose are recommended</i>
Control: Formulation blank: Treated:	6 N/A 6 <u>Bean, corn, cucumber, oilseed rape and soybean</u>	
Control: Formulation blank: Treated:	10 N/A 10	
<u>Test concentrations</u>		
Nominal:	0 (negative control), 4.07, 8.14, 16.27, 32.54, and 65.08 lbs a.i./A;	<i>Five test concentrations should be used with a dose range of 2X or 3X progression</i>
Measured:	<u>Cucumber, oat, bean, corn, onion, ryegrass and radish</u> 0, 4.24, 8.10, 16.21, 32.42 and 68.08 lb a.i./A <u>Oilseed rape, soybean and tomato</u> 0, 4.30, 6.86, 16.21, 33.04 and 68.57 lbs a.i./A	
<u>Method and interval of analytical verification</u>	Calibration standards, and matrix fortification samples were analyzed using HPLC with UV detection (205 nm)	
LOQ:	31.0 mg a.i./L	
LOD:	Set at the lowest analytical standard analyzed	

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Table 3: Experimental Parameters - Vegetative Vigor		
Parameters	Vegetative Vigor	
	Details	Remarks
		<i>Criteria</i>
Adjuvant (type, percentage, if used)	N/A	
<u>Test container (pot)</u>		Interior base of the pots was fitted with a 20 cm diameter filter paper
Size/Volume Material: (glass/polystyrene)	14 cm top diameter, 11.5 cm bottom diameter; 12 cm depth Polypropylene	<i>Non-porous containers should be used.</i> <i>OECD recommends that non-porous plastic or glazed pots be used.</i>
Growth facility	Greenhouse	
Method/depth of seeding	Seeds were planted at a depth of <i>ca.</i> 1 to 2 cm in a circular pattern around the inside perimeter of the pot.	
<u>Test material application</u> Application time including the plant growth stage Number of application Application interval Method of application	Test material was applied to the foliage after plants reached 2- to 4- leaf stage (<i>ca.</i> 2 to 3 weeks from seedling). 1 N/A; single application Applied using an application chamber with an overhead sprayer (Spray Systems Company) equipped with a conventional agricultural spray nozzle. Distance above the soil surface was not reported.	

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Table 3: Experimental Parameters - Vegetative Vigor		
Parameters	Vegetative Vigor	
	Details	Remarks
		<i>Criteria</i>
<u>Details of soil used</u> Geographic location Depth of soil collection Soil texture % sand % silt % clay pH: % organic carbon CEC Moisture at 1/3 atm (%)	Rochester, Massachusetts N/A Sandy loam 89 8 3 Not reported 1.3% Not reported Not reported	Organic matter: 2.2% <hr/> <i>EPA prefers soil mixes containing sandy loam, loam, or clay loam soil with no greater than 2% organic matter. Glass beads, rock wool, and 100% acid washed sand are not preferred..</i> <i>OECD prefers the soil to be sieved (0.5 cm) to remove coarse fragments. Carbon content should not exceed 1.5% (3% organic matter). Fine particles (under 20um) makeup should be between 10 and 20%. The recommended pH is between 5.0 and 7.5.</i>
Details of nutrient medium, if used	Each pot received <i>ca.</i> 100 mL of Peters 20-20-20 fertilizer solution.	
<u>Watering regime and schedules</u> Water source/type: Volume applied: Interval of application: Method of application:	Deionized water with nutrient medium twice weekly. All other using well water. <i>Ca.</i> 100 mL/pot Not reported. The plants were bottom-watered using subirrigation trays.	<hr/> <i>EPA prefers that under foliage watering or bottom watering be utilized for vegetative vigor studies so that the chemical is not washed out of the soil during the test.</i>
Any pest control method/fertilization, if	None used	

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Table 3: Experimental Parameters - Vegetative Vigor		
Parameters	Vegetative Vigor	
	Details	Remarks
		<i>Criteria</i>
used		
<u>Test conditions</u> Temperature: Photoperiod: Light intensity and quality: Relative humidity:	17-31°C 16L:8D Artificial lighting used to supplement natural sunlight. 6600-26000 lux 15-74%	<i>EPA prefers that the cold vs warm loving plants be tested in two separate groups to optimize plant growth.</i> <i>OECD prefers that the temperature, humidity and light conditions be suitable for maintaining normal growth of each species for the test period.</i>
<u>Reference chemical (if used)</u> Name: Concentrations:	N/A	
Other parameters, if any	None	

2. Observations:

Table 4: Observation Parameters - Vegetative Vigor		
Parameters	Vegetative Vigor	
	Details	Remarks
Parameters measured (i.e., plant height, dry weight or other endpoints)	- Survival - Phytotoxicity - Dry weight - Height	
	Survival and	

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Measurement technique for each parameter	phytotoxicity were determined visually. Height was measured (details not reported) and shoots dried ($70 \pm 5^{\circ}\text{C}$) for three days to determine dry weight.	
Observation intervals	Phytotoxicity and height were assessed weekly. Survival, height, and dry weight were determined at study termination.	
Other observations, if any	None	
Were raw data included?	Yes	
Phytotoxicity rating system, if used	0- No injury or abnormality; 100- Complete effect (dead plant)	

II. RESULTS and DISCUSSION:

A. INHIBITORY EFFECTS:

Vegetative Vigor:

All inhibitions reported below are based on comparison to the negative control.

Survival ranged from 97-100% in the negative control. There was little affect of treatment on survival with up to 3% inhibitions in corn and onion and up to 7% in soybeans; no other inhibitions in survival were noted.

Inhibitions in height ranged from 1 to 16% for bean, soybean, oat, onion and radish. Corn, tomato and oilseed rape had maximum inhibitions of 27-30% at the highest dose concentration and cucumber was most affected with inhibition of up to 45% at the highest dose concentration. Ryegrass showed promotions of 5 to 15%.

Inhibitions in dry weight ranged from 2 and 32% for oat, onion and radish. Bean, corn and soybean had inhibitions of 10 to 48% at the 8.10 lb a.i./A dose and higher, cucumber had

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inhibitions up to a maximum of 66% at the highest dose, and tomato had inhibitions that ranged from 4 to a maximum of 75% at the highest dose concentration. Ryegrass showed promotions of 24 to 51%.

Based on the study authors' results, the most sensitive monocot species was corn, based on dry weight, with NOAEC and EC₂₅ values of 4.07 and 7.0 lbs a.i./A, respectively. The most sensitive dicot species was oilseed rape, based on dry weight, with NOAEC and EC₂₅ values of 16.27 and 14 lbs a.i./A, respectively.

Morphological abnormalities (e.g. chlorosis of leaves) were determined based on a range from 0 to 100, where 0 indicates no injury or abnormality and 100 indicates complete effect (dead plant; not further described). The mean abnormality rating in the control was 3. Onion, corn, soybean, oilseed rape, bean, tomato and radish exhibited effects up to 20 and cucumber up to 60; oat and ryegrass were not affected.

B. REPORTED STATISTICS:

Survival, dry weight per replicate, and height data were analyzed. The study authors compared the negative control and formulation blank groups using a Dunnett's t-test to evaluate potential effects of inert substances contained in the end use product. No significant differences were found and all results were pooled. The LOAEC and NOAEC values were determined using a one-tailed Dunnett's test via the DUNNETT option of the GLM (general linear model) procedure of SAS version 8 ($\alpha = 0.05$ and 0.01). Estimates of the EC_x values and their confidence limits were determined using the non-linear regression analysis of Bruce and Versteeg when reductions in endpoints among one or more treatment groups were 25% or more relative to the control means. These analyses were conducted using the NLIN procedure of SAS. Nominal concentrations were used for all analyses.

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Table 5: Reported effect of Neudorff's Insecticidal Soap Concentrate (AI: potassium salts of fatty acids) on Vegetative Vigor

Species	Results summary for biomass (lbs a.i./A)								
	Weight (g)	NOAEC	EC ₀₅	95%CI	EC ₂₅	95%CI	EC ₅₀	95%CI	LOAEC
Corn	0.5317-1.0193	4.07	0.11	ND-1.2	7.0	2.4-17	>65.08	N/A	8.14
Onion	0.0177-0.0260	65.08	1.3 ¹	ND-15	>65.08	N/A	>65.08	N/A	>65.08
Ryegrass	0.0470-0.0711	65.08	>65.08	N/A	>65.08	N/A	>65.08	N/A	>65.08
Oat	0.3161-0.3695	65.08	54	ND-150	>65.08	N/A	>65.08	N/A	>65.08
Bean	0.7142-1.2410	32.54	1.7	ND-11	20	7.8-44	>65.08	N/A	65.08
Cucumber	0.2008-0.5983	16.27	9.6	ND-14	23	18-29	44	37-52	32.54
Oilseed rape	0.0870-0.6313	16.27	2.4	ND-7.1	14	7.8-23	49	29-82	32.54
Radish	0.1986-0.2795	16.27	14	7.3-20	55	46.66	>65.08	N/A	32.54
Soybean	0.3703-0.7591	16.27	8.2	ND-14	29	21-38	>65.08	N/A	32.54
Tomato	0.0470-0.1866	16.27	7.1	ND-13	19	11-29	38	28-54	32.54

1 Estimated using linear-regression.

N/A – Not Applicable; EC value was empirically estimated; therefore, corresponding 95% confidence limits could not be calculated.

ND – Not determined; Corresponding 95% confidence limit could not be determined.

Table 5a: Reported effect of Neudorff's Insecticidal Soap Concentrate (AI: potassium salts of fatty acids) on Vegetative Vigor

Species	Results summary for height (lbs a.i./A)								
	Height(cm)	NOEC	EC ₀₅	95%CI	EC ₂₅	95%CI	EC ₅₀	95%CI	LOEC
Corn	48.0-65.8	4.07	2.1	0.24-5.9	64	36-100	>65.08	N/A	8.14
Onion	17.3-19.2	65.08	3.3	ND-140	>65.08	N/A	>65.08	N/A	>65.08
Ryegrass	26.2-30.2	65.08	>65.08	N/A	>65.08	N/A	>65.08	N/A	>65.08
Oat	47.1-52.0	65.08	>65.08	N/A	>65.08	N/A	>65.08	N/A	>65.08
Bean	11.1-13.3	65.08	35	ND-110	>65.08	N/A	>65.08	N/A	>65.08
Cucumber	3.8-6.9	16.27	15	9.5-19	38	34-43	>65.08	N/A	32.54
Oilseed rape	4.6-6.8	16.27	12	5.6-18	46	38-55	>65.08	N/A	32.04

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Table 5a: Reported effect of Neudorff's Insecticidal Soap Concentrate (AI: potassium salts of fatty acids) on Vegetative Vigor

Species	Results summary for height (lbs a.i./A)								
	Height(cm)	NOEC	EC ₀₅	95%CI	EC ₂₅	95%CI	EC ₅₀	95%CI	LOEC
Radish	2.9-3.4	65.08	12	0.042-120	>65.08	N/A	>65.08	N/A	>65.08
Soybean	17.4-25.0	32.54	28	ND-44	>65.08	N/A	>65.08	N/A	65.08
Tomato	5.6-8.4	32.54	13	ND-26	53	34-76	>65.08	N/A	65.08

N/A – Not Applicable; EC value was empirically estimated; therefore, corresponding 95% confidence limits could not be calculated.

ND – Not determined; Corresponding 95% confidence limit could not be determined.

Table 5b: Reported effect of Neudorff's Insecticidal Soap Concentrate (AI: potassium salts of fatty acids) on Vegetative Vigor

Species	Results summary for survival (lbs a.i./A)								
	%	NOEC	EC ₀₅	95%CI	EC ₂₅	95%CI	EC ₅₀	95%CI	LOEC
Corn	100	ND	ND	N/A	ND	N/A	ND	N/A	ND
Onion	91-100	ND	ND	N/A	ND	N/A	ND	N/A	ND
Ryegrass	100	ND	ND	N/A	ND	N/A	ND	N/A	ND
Oat	100	ND	ND	N/A	ND	N/A	ND	N/A	ND
Bean	97-100	ND	ND	N/A	ND	N/A	ND	N/A	ND
Cucumber	100	ND	ND	N/A	ND	N/A	ND	N/A	ND
Oilseed rape	100	ND	ND	N/A	ND	N/A	ND	N/A	ND
Radish	100	ND	ND	N/A	ND	N/A	ND	N/A	ND
Soybean	93-100	ND	ND	N/A	ND	N/A	ND	N/A	ND
Tomato	100	ND	ND	N/A	ND	N/A	ND	N/A	ND

Plant injury index

Control	Onion	Ryegrass	Oat	Corn	Cucumber	Soybean	Oilseed Rape	Bean	Tomato	Radish	Formulation Blank
0-3	0-12	0	0	0-20	0-60	0-13	0-20	0-13	0-13	0-20	N/A

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Plant injury index

0- No effect; 10-30- Slight effect; 40-60- Moderate effect; 70-90- Severe effect; 100- Complete effect

C. VERIFICATION OF STATISTICAL RESULTS BY THE REVIEWER:

All analyses were conducted using the negative control only. Analysis was conducted using Sprouts, a SAS program provided by EFED/OPP/USEPA, in SAS version 9. All endpoints for which replicate data were provided were examined graphically using graphs to determine if they exhibited a dose-dependent response, which was ultimately used to select the multiple comparison tests to detect the NOAEC. Data for each endpoint were tested to determine if their distributions were normal and if their variances were homogeneous using Shapiro-Wilk's and Levene's tests, respectively. Data that satisfied these assumptions were subjected to Dunnett's and William's tests and data that did not satisfy these assumptions were subjected to the non-parametric MannWhitney-U and Jonckheere's tests. Visual examinations of the Sprouts output in SAS were used to determine if there were significant differences between the negative and adjuvant controls.

All analyses were conducted using the mean measured application rates of lbs active ingredient per acre (lbs a.i./A).

Data Evaluation Report on the Toxicity of Neudorff's Insecticidal Soap Concentrate (AI: potassium salts of fatty acids) to Terrestrial Vascular Plants: Vegetative Vigor

PMRA Submission Number {.....}

EPA MRID Number 48402302

Table 6: Effect of Neudorff's Insecticidal Soap Concentrate (AI: potassium salts of fatty acids) on Vegetative Vigor										
Species	Results summary for biomass (lbs a.i./A)									
	Weight (g)	NOAEC	EC ₀₅	95% CI	EC ₂₅	95% CI	EC ₅₀	95% CI	slope	95% CI
Corn	0.5317-1.0193	4.239	0.082	0.0012-5.42	5.91	1.11-31.45	115.38*	30.60-435.10	0.5225	0.3158-1.5125
Onion ¹	0.0177-0.0260	8.104	>68.08	N/A	>68.08	N/A	>68.08	N/A	N/A	N/A
Ryegrass	0.0470-0.0711	68.08	>68.08	N/A	>68.08	N/A	>68.08	N/A	N/A	N/A
Oat	0.3161-0.3695	68.08	>68.08	N/A	>68.08	N/A	>68.08	N/A	N/A	N/A
Bean ²	0.7142-1.2410	8.104	1.43	0.018-112.06	20.72	3.38-127.07	133.10*	25.91-683.86	0.8351	0.3964- -7.7995
Cucumber	0.2008-0.5983	16.208	8.89	4.64-17.04	23.05	16.21-32.79	44.70	36.75-54.37	2.3457	1.7536-3.513
Oilseed rape	0.0870-0.6313	<4.3013	4.38	0.83-23.03	18.50	7.93-43.11	50.31	31.93-79.27	1.5519	0.9645-3.9693
Radish	0.1986-0.2795	16.208	13.53	6.54-27.98	57.27	45.50-72.08	156.15*	101.42-240.39	1.5483	1.0792-2.7392
Soybean	0.3703-0.7591	16.208	8.84	3.19-24.49	30.55	19.49-47.87	72.34	54.56-95.90	1.8015	1.1982-3.689
Tomato	0.0470-0.1866	16.208	8.90	3.28-24.16	21.73	12.41-38.04	40.40	29.41-55.49	2.5044	1.6385-5.3112

1 Convergence criteria met but problems with the model were indicated as data were extremely variable.

2 The data was not monotonically decreasing. A maximum inhibition of 34% was present at the highest test level.

* Toxicity value should be interpreted with great caution as the value is not bracketed by the test concentrations.

Data Evaluation Report on the Toxicity of Neudorff's Insecticidal Soap Concentrate (AI: potassium salts of fatty acids) to Terrestrial Vascular Plants: Vegetative Vigor

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EPA MRID Number 48402302

Table 6a: Effect of Neudorff's Insecticidal Soap Concentrate (AI: potassium salts of fatty acids) on Vegetative Vigor										
Species	Results summary for height (lbs a.i./A)									
	Height(cm)	NOAEC	EC ₀₅	95% CI	EC ₂₅	95% CI	EC ₅₀	95% CI	slope	95% CI
Corn	48.0-65.8	4.239	2.28	0.40-15.27	66.69	33.18-134.06	697.47*	164.71-2953.42	0.6616	0.4325- -1.4075
Onion ¹	17.3-19.2	68.08	3.57	0.0011-11475.67	>68.08	NC	>68.08	NC	0.2735	0.0779- -0.1809
Ryegrass	26.2-30.2	68.08	>68.08	N/A	>68.08	N/A	>68.08	N/A	N/A	N/A
Oat	47.1-52.0	68.08	>68.08	N/A	>68.08	N/A	>68.08	N/A	N/A	N/A
Bean	11.1-13.3	68.08	>68.08	N/A	>68.08	N/A	>68.08	N/A	N/A	N/A
Cucumber	3.8-6.9	16.208	13.68	8.61-21.74	38.53	31.80-46.68	79.14*	68.46-91.49	2.1577	1.6701-3.0473
Oilseed rape	4.6-6.8	16.208	11.50	5.16-25.64	48.08	36.79-62.83	129.93	89.10-189.48	1.5621	1.0845-2.7918
Radish ¹	2.9-3.4	68.08	12.18	0.013-11018.50	17046.95*	NC	>68.08	NC	0.3085	0.0790- -0.1619
Soybean	17.4-25.0	33.039	29.91	4.46-200.54	62.24	26.20-107.03	103.58*	34.58-310.25	3.0493	0.9363- -2.4265
Tomato	5.6-8.4	33.039	14.48	3.23-64.93	56.31	35.22-90.03	144.76*	60.75-344.94	1.6450	0.8452-30.5641

¹ The model converged but EC values were outside the range of concentrations or unreliable and slope and 95% C.I. are not likely to be reliable either.

* Toxicity value should be interpreted with caution as it is not bracketed by the test concentrations.

N/A Since less than the defined percent inhibition was observed, the EC₀₅, EC₂₅ and EC₅₀ values were empirically estimated, therefore, 95% confidence limits could not be determined

NC- not calculable; referring to cases where the value was so extreme as to be deemed unreliable.

Data Evaluation Report on the Toxicity of Neudorff's Insecticidal Soap Concentrate (AI: potassium salts of fatty acids) to Terrestrial Vascular Plants: Vegetative Vigor

PMRA Submission Number {.....}

EPA MRID Number 48402302

Table 6b: Effect of Neudorff's Insecticidal Soap Concentrate (AI: potassium salts of fatty acids) on Vegetative Vigor										
Species	Results summary for survival (lbs a.i./A)									
	%	NOAEC	EC ₀₅	95%CI	EC ₂₅	95%CI	EC ₅₀	95%CI	slope	95%CI
Corn	100	68.08	>68.08	N/A	>68.08	N/A	>68.08	N/A	N/A	N/A
Onion ¹	91-100	68.08	>68.08	N/A	>68.08	N/A	>68.08	N/A	0.0680	0.0026-1.7695
Ryegrass	100	68.08	>68.08	N/A	>68.08	N/A	>68.08	N/A	N/A	N/A
Oat	100	68.08	>68.08	N/A	>68.08	N/A	>68.08	N/A	N/A	N/A
Bean ¹	97-100	68.08	>68.08	N/A	>68.08	N/A	>68.08	N/A	2.1088	0.1124-39.5494
Cucumber ¹	97-100	68.08	>68.08	N/A	>68.08	N/A	>68.08	N/A	9.99	N/A
Oilseed rape	100	68.57	>68.57	N/A	>68.57	N/A	>68.57	N/A	N/A	N/A
Radish	100	68.08	>68.08	N/A	>68.08	N/A	>68.08	N/A	N/A	N/A
Soybean ¹	93-100	68.57	49.78	NC	695.56*	NC	4349.06*	NC	7.0353	0.4709-105.1136
Tomato	100	68.57	>68.57	N/A	>68.57	N/A	>68.57	N/A	N/A	N/A

¹ The model converged but EC values were outside the range of concentrations or were unreliable and slope and 95% C.I. are not likely to be reliable either.

* Toxicity value should be interpreted with great caution as the value is not bracketed by the test concentrations.

N/A Since less than the defined percent inhibition was observed, the EC₀₅, EC₂₅ and EC₅₀ values were empirically estimated, therefore, 95% confidence limits could not be determined

Data Evaluation Report on the Toxicity of Neudorff's Insecticidal Soap Concentrate (AI: potassium salts of fatty acids) to Terrestrial Vascular Plants: Vegetative Vigor

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Plant Injury Index											
Control	Onion	Ryegrass	Oat	Corn	Cucumber	Soybean	Oilseed Rape	Bean	Tomato	Radish	Formulation Blank
0-3	0-12	0	0	0-20	0-60	0-13	0-20	0-13	0-13	0-20	N/A

0- No effect; 10-30- Slight effect; 40-60- Moderate effect; 70-90- Severe effect; 100- Complete effect

Most sensitive monocot: Corn; dry weight

EC₅₀/IC₅₀: >68.08 lbs a.i./A 95% C.I.: N/A
 EC₂₅/IC₂₅: 5.91 lbs a.i./A 5% C.I.: 1.11-31.45 lbs a.i./A*
 EC₀₅/IC₀₅: 0.082 lbs a.i./A* 95% C.I.: 0.0012-5.42 lbs a.i./A*
 NOAEC: 4.239 lbs a.i./A
 Slope: 0.5225 Std err: 0.3158-1.5125

Most sensitive dicot: Oilseed Rape; dry weight

EC₅₀/IC₅₀: 50.31 lbs a.i./A 95% C.I.: 31.93-79.27 lbs a.i./A*
 EC₂₅/IC₂₅: 18.50 lbs a.i./A 95% C.I.: 7.93-43.11 lbs a.i./A
 EC₀₅/IC₀₅: 4.38 lbs a.i./A 95% C.I.: 0.83-23.03*
 NOAEC: <4.3013 lbs a.i./A
 Slope: 1.55 Std err: 0.96-3.97

D. STUDY DEFICIENCIES:

Deviations from OCSPP 850.4150 were noted:

1. Only 3, 5 or 8 seedlings per replicate were tested; OPPTS guidelines suggest a minimum of 10 seedlings per replicate.
2. The percent organic carbon, cation exchange capacity, and moisture content of the soil were not reported.
3. The physico-chemical properties of the test material were not reported.
4. Relative humidity ranged from 15 to 74%; OPPTS guidelines suggest that relative humidity should approach 70 ± 5% during light periods and 90% during dark periods. The study authors did not differentiate between day and night humidity readings.
5. The test temperatures ranged from 17 to 31°C daytime and 17-24°C nighttime; OPPTS guidelines suggest day temperatures of 25 ± 3°C and night temperatures of 20 ± 3°C.

These deviations were minor and do not impact the acceptability of the study.

* Test concentration and 95% confidence interval not bracketed by the tested dose range.

Data Evaluation Report on the Toxicity of Neudorff's Insecticidal Soap Concentrate (AI: potassium salts of fatty acids) to Terrestrial Vascular Plants: Vegetative Vigor

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E. REVIEWER'S COMMENTS:

The reviewer's and the study authors' results were in agreement with regard to the most sensitive monocot and dicot species. For the most sensitive monocot, the reviewer obtained the same NOAEC value, and the EC₂₅ values were very similar. For the most sensitive dicot, the reviewer's estimate of the NOAEC was lower; however, the EC₂₅ values were again similar. The reviewer was able to obtain confidence intervals and a slope value for the most sensitive species; therefore, the reviewer's results are presented in the Executive Summary and Conclusions sections of this DER.

Based on the study authors' results, the most sensitive monocot species was corn, based on dry weight, with NOAEC and EC₂₅ values of 4.07 and 7.0 lbs a.i./A, respectively. The most sensitive dicot species was oilseed rape, based on dry weight, with NOAEC and EC₂₅ values of 16.27 and 14 lbs a.i./A, respectively. These toxicity values were determined based on nominal concentrations.

F. CONCLUSIONS:

The study is scientifically sound and fulfills EPA guideline requirements for a vegetative vigor toxicity test with terrestrial plants. The most sensitive monocot species was corn, based on dry weight, with NOAEC and EC₂₅ values of 4.239 and 5.9 lbs a.i./A, respectively. The most sensitive dicot species was oilseed rape, based on dry weight, with NOAEC and EC₂₅ values of <4.3013 and 18.5 lbs a.i./A, respectively.

Most sensitive monocot and EC₂₅: Corn (dry weight; 5.9 lbs a.i./A)

Most sensitive dicot and EC₂₅: Oilseed rape (dry weight; 18.5 lbs a.i./A)

III. REFERENCES:

U.S. Environmental Protection Agency. 2012. Ecological Effects Test Guidelines. OCSPP 850.4150, Vegetative Vigor

U.S. Environmental Protection Agency. 2012. Ecological Effects Test Guidelines. OCSPP 850.4000, Background and Special Considerations- Tests with Terrestrial and Aquatic Plants, Cyanobacteria, and Terrestrial Soil-Core Microcosms.

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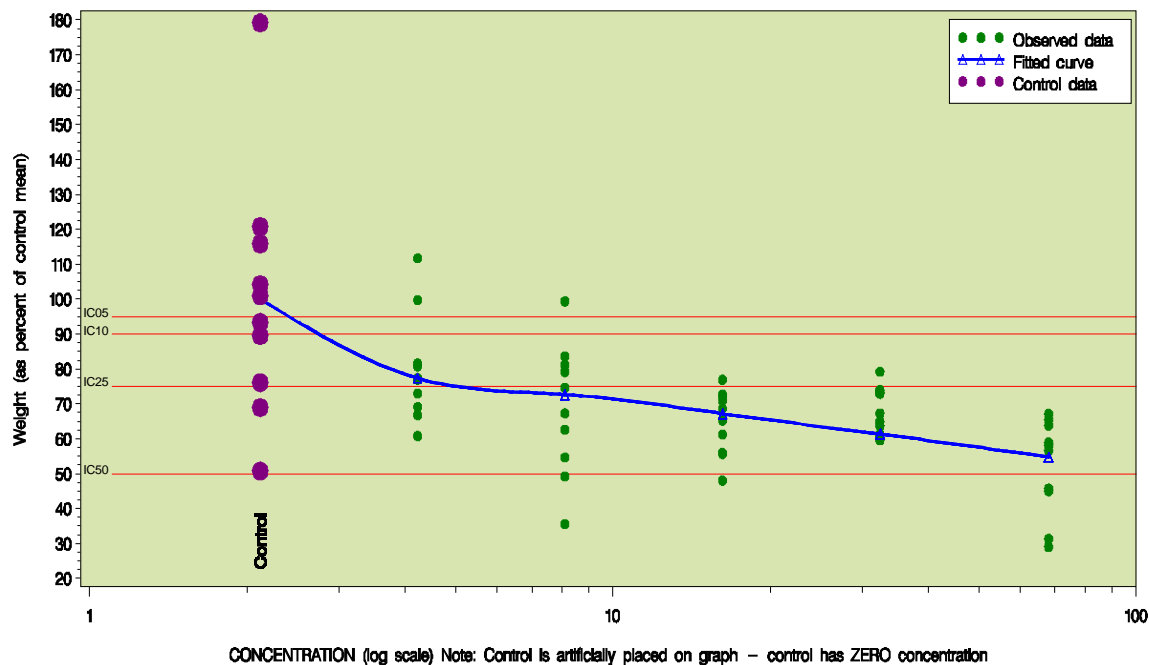
PMRA Submission Number {.....}

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APPENDIX I. OUTPUT OF REVIEWER'S STATISTICAL VERIFICATION:

Weight Inhibition Concentrations (ICx) for Corn

VEGETATIVE VIGOR (Soapy Salts) 079021 48402302 (SAS v9.2, Sprouts v1.0) 23NOV2011



Data Evaluation Report on the Toxicity of Neudorff's Insecticidal Soap Concentrate (AI: potassium salts of fatty acids) to Terrestrial Vascular Plants: Vegetative Vigor

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Analysis results for Variable: **WEIGHT Corn**

(SAS v9.2, Sprouts v1.0) VEGETATIVE VIGOR (Soapy Salts) 079021 48402302 23NOV2011

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS

Shapiro-Wilks test for Normality of Residuals --- alpha-level=.01

Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=.05

Use parametric analysis if neither test rejected, otherwise non-parametric analyses.

Shapiro-Wilks Shapiro-Wilks Levenes Levenes Conclusion

Test Stat P-value Test Stat P-value

0.910 <.001 2.993 0.019 USE NON-PARAMETRIC TESTS

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	CV(%)	95% Confidence Interval
-1.000000	10	1.019280	0.357620	0.113089	35.09	0.763454, 1.275106
4.239000	10	0.813470	0.156560	0.049509	19.25	0.701474, 0.925466
8.104000	10	0.700770	0.191442	0.060539	27.32	0.563821, 0.837719
16.208000	10	0.660390	0.094371	0.029843	14.29	0.592881, 0.727899
32.416000	10	0.689950	0.069332	0.021925	10.05	0.640353, 0.739547
68.080000	10	0.531710	0.140135	0.044315	26.36	0.431464, 0.631956

Level	Median	Min	Max	%of Ctrl(means)	%Reduction(means)
-1.000000	0.990700	0.518100	1.826500	.	.
4.239000	0.787050	0.620100	1.138900	79.81	20.19
8.104000	0.723550	0.362700	1.013200	68.75	31.25
16.208000	0.682750	0.490000	0.784100	64.79	35.21
32.416000	0.674350	0.607400	0.807700	67.69	32.31
68.080000	0.585000	0.296300	0.685000	52.17	47.83

Analysis results for Variable: **WEIGHT Corn**

NON-PARAMETRIC ANALYSES - use alpha-level=.05 for all tests

Kruskal-Wallis test - testing if at least one group differs signif. from others

Exact p-value Conclusion

<.0001 At least one group differs

Mann-Whitney-Wilcoxon (NO Bonf. adj) - test if each trt is signif. less than control

Jonckheere - Check plots! Test assumes a monotonically decreasing response. Testing neg. trend

Level	Median	%Reduc Ctrl	MannWW	Level	Median	Jonckheere
	(medians)	Exact p				
		(NO Bonf)			p-value	

Data Evaluation Report on the Toxicity of Neudorff's Insecticidal Soap Concentrate (AI: potassium salts of fatty acids) to Terrestrial Vascular Plants: Vegetative Vigor

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Ctrl	0.990700	.	.	Ctrl	0.990700	.
4.239000	0.787050	20.56	0.072	4.239000	0.787050	0.065
8.104000	0.723550	26.97	0.009	8.104000	0.723550	0.007
16.20800	0.682750	31.08	0.003	16.20800	0.682750	<.001
32.41600	0.674350	31.93	0.003	32.41600	0.674350	<.001
68.08000	0.585000	40.95	<.001	68.08000	0.585000	<.001

RESULTS SUMMARY	NOAEC	LOAEC
Mann Whitney Test	4.239	8.104
Jonckheere-Terpstra Test	16.208	32.416

PARAMETER ESTIMATES FROM NONLINEAR MODELING

NOTE: Convergence criterion met.

WARNING: Do NOT report values below if convergence failed or convergence problems were noted.

Note that convergence does not necessarily mean a good model fit and/or good estimates!
 LOOK AT GRAPHS! DO ESTIMATES MAKE SENSE? ICx estimates that fall outside the range of concentrations tested (along with their slope and CIs) are not likely to be reliable.

	Estimate	LowerCL	UpperCL
IC50	115.3806891	30.5968403	435.1005944
IC25	5.9050047	1.1085459	31.4547925
IC10	0.4067270	0.0166715	9.9227067
IC05	0.0820333	0.0012405	5.4249237

Slope	(LowerCI	UpperCI)
0.5225	0.3158	1.5125

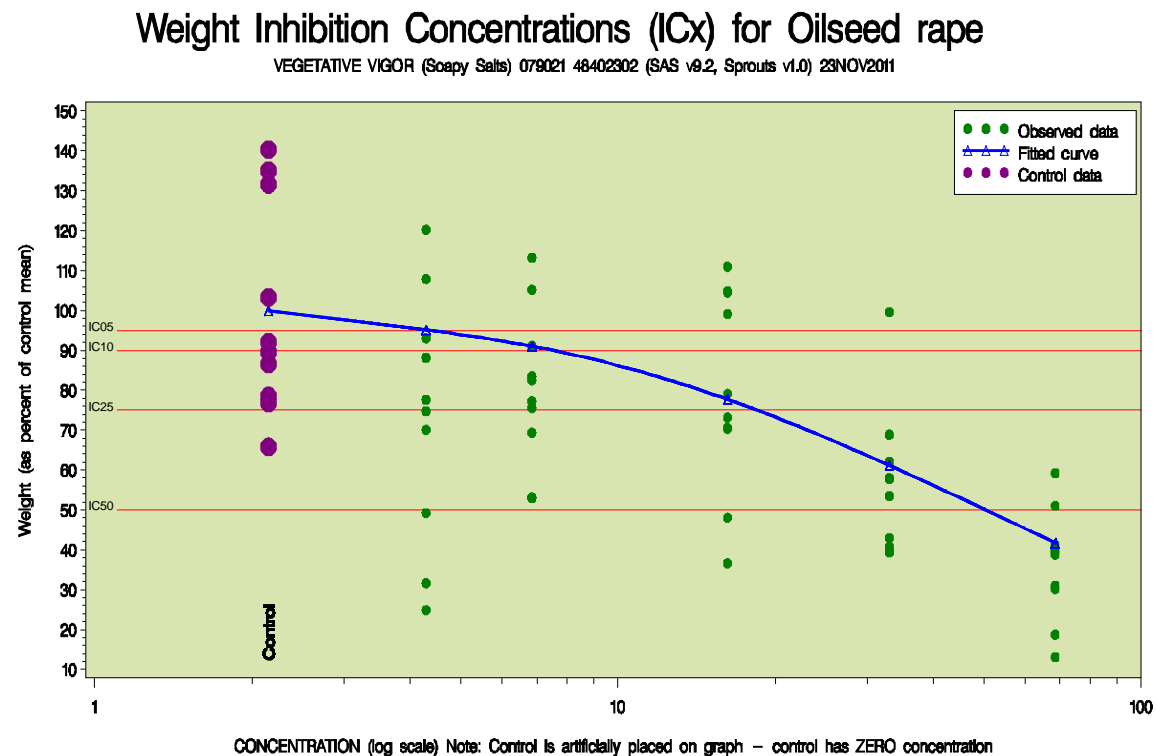
OBSERVED vs PREDICTED TREATMENT GROUP MEANS

Level	N	Observed Mean	Predicted Mean	(Obs-Pred) of Ctrl	Pred % from Ctrl	Pred % Reduc
-1.000000	10	1.02	1.02	0.00	99.98	0.02
4.239000	10	0.81	0.79	0.03	77.31	22.69
8.104000	10	0.70	0.74	-0.04	72.65	27.35
16.208000	10	0.66	0.68	-0.02	67.18	32.82
32.416000	10	0.69	0.63	0.06	61.32	38.68
68.080000	10	0.53	0.56	-0.03	54.75	45.25

Data Evaluation Report on the Toxicity of Neudorff's Insecticidal Soap Concentrate (AI: potassium salts of fatty acids) to Terrestrial Vascular Plants: Vegetative Vigor

PMRA Submission Number {.....}

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Data Evaluation Report on the Toxicity of Neudorff's Insecticidal Soap Concentrate (AI: potassium salts of fatty acids) to Terrestrial Vascular Plants: Vegetative Vigor

PMRA Submission Number {.....}

EPA MRID Number 48402302

Analysis results for Variable: **WEIGHT Oilseed rape**

(SAS v9.2, Sprouts v1.0) VEGETATIVE VIGOR (Soapy Salts) 079021 48402302 23NOV2011

TESTS OF ASSUMPTIONS FOR PARAMETRIC ANALYSIS

Shapiro-Wilks test for Normality of Residuals --- alpha-level=.01

Levenes test for homogeneity of variance(absolute residuals) -- alpha-level=.05

Use parametric analysis if neither test rejected, otherwise non-parametric analyses.

Shapiro-Wilks Shapiro-Wilks Levenes Levenes Conclusion

Test Stat P-value Test Stat P-value

0.985 0.660 1.665 0.159 USE PARAMETRIC TESTS

BASIC SUMMARY STATISTICS

Level	N	Mean	StdDev	StdErr	CV(%)	95% Confidence Interval
-1.000000	10	0.631300	0.168139	0.053170	26.63	0.511021, 0.751579
4.301300	10	0.465760	0.196294	0.062074	42.14	0.325340, 0.606180
6.857000	10	0.507670	0.124046	0.039227	24.43	0.418933, 0.596407
16.208000	10	0.503560	0.158520	0.050128	31.48	0.390162, 0.616958
33.039000	10	0.355160	0.116526	0.036849	32.81	0.271802, 0.438518
68.570000	10	0.229320	0.086994	0.027510	37.94	0.167088, 0.291552

Level	Median	Min	Max	%of Ctrl(means)	%Reduction(means)
-1.000000	0.573350	0.415900	0.886300	.	.
4.301300	0.481000	0.157200	0.759400	73.78	26.22
6.857000	0.504550	0.334900	0.715000	80.42	19.58
16.208000	0.480800	0.231500	0.700900	79.77	20.23
33.039000	0.351400	0.248600	0.628800	56.26	43.74
68.570000	0.247400	0.082900	0.374200	36.33	63.67

Analysis results for Variable: **WEIGHT Oilseed rape**

PARAMETRIC ANALYSES - use alpha-level=0.05 for all tests

Analysis of Variance (ANOVA) - overall F-test

Numerator df	Denominator df	F-stat	P-value
5	54	9.06	<.0001

Dunnett -testing if each trt mean is significantly less than control

Williams-tests neg. trend. Check plots! TEST ASSUMES A MONOTONICALLY DECREASING DOSE RESPONSE.

Level	Mean	%Reduc	Ctrl	Dunnett	Level	Isotonic	Williams
	(means)			p-value	mean	p-value	

Data Evaluation Report on the Toxicity of Neudorff's Insecticidal Soap Concentrate (AI: potassium salts of fatty acids) to Terrestrial Vascular Plants: Vegetative Vigor

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Ctrl	0.631300	.	.	Ctrl	.	.
4.301300	0.465760	26.22	0.029	4.301300	0.492330	0.019
6.857000	0.507670	19.58	0.112	6.857000	0.492330	0.022
16.20800	0.503560	20.23	0.100	16.20800	0.492330	0.023
33.03900	0.355160	43.74	<.001	33.03900	0.355160	<.001
68.57000	0.229320	63.67	<.001	68.57000	0.229320	<.001

RESULTS SUMMARY	NOAEC	LOAEC
Dunnetts Test	<lowest dose	4.3013
Williams Test	<lowest dose	4.3013

MSD=The minimum diff Dunnett's was able detect as being statistically significant at .05

MSD: 0.15 %Change from ctrl the MSD represents: 23.73

PARAMETER ESTIMATES FROM NONLINEAR MODELING

NOTE: Convergence criterion met.

WARNING: Do NOT report values below if convergence failed or convergence problems were noted.

Note that convergence does not necessarily mean a good model fit and/or good estimates!

LOOK AT GRAPHS! DO ESTIMATES MAKE SENSE? ICx estimates that fall outside the range of

concentrations tested (along with their slope and CIs) are not likely to be reliable.

	Estimate	LowerCL	UpperCL
IC50	50.3125379	31.9324524	79.2720661
IC25	18.4947182	7.9348572	43.1078460
IC10	7.5136307	1.9569704	28.8479819
IC05	4.3827805	0.8341656	23.0275210

Slope (LowerCI , UpperCI)

1.5519 0.9645 3.9693

OBSERVED vs PREDICTED TREATMENT GROUP MEANS

Level	N	Observed Mean	Predicted Mean	(Obs-Pred) of Ctrl	Pred % from Ctrl	Pred % Reduc
-1.000000	10	0.63	0.58	0.05	91.38	8.62
4.301300	10	0.47	0.55	-0.08	86.92	13.08
6.857000	10	0.51	0.53	-0.02	83.19	16.81
16.208000	10	0.50	0.45	0.06	71.04	28.96
33.039000	10	0.36	0.35	0.00	55.88	44.12
68.570000	10	0.23	0.24	-0.01	38.14	61.86